8EHQ-0892-12848

UNION CARBIDE

"Contains NO CBI"

UNION CARBIDE CHEMICALS AND PLASTICS COMPANY INC.
HEALTH, SAFETY AND ENVIRONMENTAL AFFAIRS

A

ORIGINAL

August 21, 1992

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Room L-100
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

8ECAP

92 AUG 27 PM 1:53

Attn: Section 8(e) Coordinator (CAP Agreement)

Re: CAP Agreement Identification No. 8ECAP-0110

Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following report pursuant to the terms of the TSCA §8(e) Compliance Audit Program and Union Carbide's CAP Agreement dated August 14, 1991 (8ECAP-0110). This report describes acute toxicity studies with naphthalene acetic acid, sodium salt (CASRN 61-31-4).

"NAA (Naphthalene Acetic Acid) Sodium Salt: Acute Toxicity and Irritancy Studies", Bushy Run Research Center, Project Report 45-45, April 23, 1982.

A complete summary of this report is attached.

Previous TSCA Section 8(e) or "FYI" Submission(s) related to this substance are:

(None)

Previous PMN submissions related to this substance are: (None)

DISCLOSURE REVIEW 3/23/95

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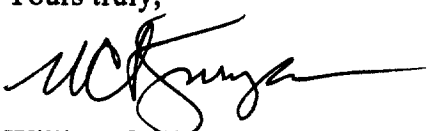
8EHQ-92-12848
INIT 08/27/92

45-45

This information is submitted in light of EPA's current guidance. Union Carbide does not necessarily agree that this information reasonably supports the conclusion that the subject chemical presents a substantial risk of injury to health or the environment.

In the attached report the term "CONFIDENTIAL" may appear. This precautionary statement was for internal use at the time of issuance of the report. Confidentiality is hereby waived for purposes of the needs of the Agency in assessing health and safety information. The Agency is advised, however, that the publication rights to the contained information are the property of Union Carbide.

Yours truly,



William C. Kuryla, Ph.D.
Associate Director
Product Safety
(203/794-5230)

WCK/cr
Attachment (3 copies of cover letter, summary, and report)

SUMMARY

BUSHY RUN RESEARCH CENTER

R. D. 4, Mellon Road, Export, Pennsylvania 15632 Telephone (412) 327-1020

Project Report 45-45

NAA (Naphthalene Acetic Acid) Sodium Salt

Acute Toxicity and Irritancy Studies

Sponsor: Union Carbide Agricultural Products Company

* * * * *

Summary

Rat peroral toxicity, rabbit percutaneous toxicity, rabbit skin irritancy and rabbit eye irritancy tests were completed on NAA Sodium Salt. The procedures followed for these tests were based on the proposed Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) guidelines. Results from this study, expressed in terms of sample as received, are as follows:

Peroral, Rat (Fasted)
Males: LD50 = 1.35 g of NAA Sodium Salt per kg of body weight (b.w.).
Females: LD50 = 0.933 g of NAA Sodium Salt per kg b.w.

Percutaneous, Rabbit
Males, abraded: LD50 >2.0 g of NAA Sodium Salt per kg b.w.
Females, abraded: LD50 > 2.0 g of NAA Sodium Salt per kg b.w.

Skin Irritation, Rabbit
No reaction on any of 6 rabbits from 0.5 g of NAA Sodium Salt.

Eye Irritation, Rabbit
Corneal opacity, iritis, conjunctival redness, chemosis and discharge in all 9 eyes from 0.1 g per eye. Injury persisted in 5 eyes through 21 days.

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BUSHY RUN RESEARCH CENTER

R. D. 4, Mellon Road, Export, Pennsylvania 15632 Telephone (412) 327-1020

Project Report 45-45
23 Pages
Tel: (412) 327-1020
April 23, 1982

NAA (Naphthalene Acetic Acid) Sodium Salt

Acute Toxicity and Irritancy Studies

Sponsor: Union Carbide Agricultural Products Company

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Corneal opacity, iritis, conjunctival redness, chemosis and discharge in all 9 eyes from 0.1 g per eye. Injury persisted in 5 eyes through 21 days.

Objective

The purpose of this study was to assess the acute peroral toxicity, percutaneous toxicity, dermal irritancy and ocular irritancy of NAA Sodium Salt according to guidelines proposed by FIFRA in the Federal Register, Vol. 43, No. 163, August 22, 1978.

Materials

Approximately 600 grams of Naphthalene Acetic Acid (NAA) Sodium Salt was received from Union Carbide Corporation, Ambler, PA on December 3, 1981. The sample, as received by the Bushy Run Research Center (BRRC), was a white powdery solid. BRRC Sample No. 44-356 was assigned to this material. The container bore the analysis of 95% of active ingredient and the Lot No. 0-81-151. The CAS Number was not available. The BRRC Project Number for acute work on NAA Sodium Salt is 82-03-10743.

For the skin irritation and the percutaneous toxicity tests, the sample was moistened with saline (commercial 0.9% NaCl). Solutions of NAA Sodium Salt in water (deionized water prepared by BRRC) were used for the peroral test and were prepared freshly for each day of dosing. The dry powder was used to dose the rabbit eyes. Representative samples of the test material and the test material incorporated into the water were saved and stored in glass bottles. They will be kept in an appropriate storage cabinet at BRRC.

Experimental Animals

Rats

Male and female Hilltop-Wistar albino rats, weighing between 200 and 250 grams (approximately 5 to 7 weeks of age), were used because of this laboratory's past experience with this species and strain. The rats were obtained from Hilltop Lab Animals (Scottdale, PA) and were acclimatized for at least 5 days before they were dosed. Upon receipt, they were housed in Room 109, where they were subsequently dosed and observed until death or sacrifice. All rats were assigned unique animal numbers and were identified by toe clipping.

The rats were housed in cages, 2 to 5 per cage, with wire floors under which deotized animal cage board (Shepherd Specialty Papers, Inc., Kalamazoo, MI) was placed. They were maintained on Agway certified rodent chow and water provided by an automatic water system. The feed was available ad libitum until the day before dosing and again following dosing. Water was supplied by the Municipal Authority of Westmoreland County (Greensburg, PA) and was available at all times except during the actual dosing period. Recent water analyses indicated no contaminants, in the judgment of the Study Director, that interfered with the conduct of the peroral test. Temperatures ranged from approximately 71°F to

77°F during the test period; relative humidity readings were approximately 20% to 59%. Room lights were on for 12 hours and off for 12 hours (timed automatically) and dosing was completed at approximately 3.0 to 5.0 hours after the lights were switched on.

The rats were weighed and inspected for health on the day of the test. Those not exhibiting a healthy state were not used. Animals were not selected through a formal randomization system, but were designated for dosing according to need and availability. A total of 20 male rats and 15 female rats were used for the peroral testing. The rats not assigned to this study were considered available for other toxicity testing.

Rabbits

Male and female New Zealand White rabbits from Three Springs Kennels (Jackson Center, PA), weighing 2.0 to 3.0 kg (approximately 12 to 18 weeks of age), were used. These animals were used because of this laboratory's past experience with this species and strain. The rabbits were acclimatized for at least 5 days before they were dosed. Upon receipt, they were housed in a holding area (Room 101 or Room 102) separated from the dosing and observation area (Room 122). Each rabbit received a unique identification number which was marked in indelible ink on one ear and on the animal cage card.

The rabbits were housed individually in cages with wire floors under which deotized animal cage board (Shepherd Specialty Papers, Inc.) was placed. They were maintained on Big Red Maintenance Diet (Agway) and water provided by an automatic water system or individual water pans as appropriate. Water was supplied by the Municipal Authority of Westmoreland County (Greensburg, PA). Both feed and water were available ad libitum except during dosing periods. Recent water analyses indicated no contaminants, in the opinion of the Study Director, that interfered with the conduct of the dermal or eye tests. Temperatures ranged from approximately 75°F to 82°F during the test period; relative humidity readings were approximately 26% to 55%. Room lights were on for 12 hours and off for 12 hours (timed automatically) and dosing was completed at approximately 3.0 to 7.0 hours after the lights were switched on.

The rabbits were weighed and inspected on the day of the test. Those not exhibiting a healthy state were not used. They were not selected through a formal randomization system, but were designated for dosing according to need and availability. A total of 10 males and 15 females were used for the rabbit tests. Those not assigned to this study were considered available for other toxicity testing.

Test Procedures

All procedures were based on the proposed FIFRA guidelines (1978).

Peroral Intubation

An appropriate amount of sample was weighed and mixed with sufficient water to give a 15% w/v solution (1 ml solution = 0.15 g sample). This solution was placed on a magnetic stirrer for approximately one-half hour before dosing.

The resulting solution was administered by stomach intubation through a commercial 15 or 16 gauge (3 in.) ball-end stainless steel needle (Popper and Sons, Inc., New Hyde Park, NY) attached to a disposable syringe (Becton-Dickinson, Rutherford, NJ). The exact amounts of sample and solution given to each rat were recorded on the dosing sheet (available to the sponsor on request).

For the LD50 test, 5 male and 5 female rats were included on each dosage level. They were fasted overnight (approximately 18 hours) before dosing. Dosage levels were varied (using different volumes) by a constant factor until sufficient mortality data were collected to calculate an LD50. Dosed rats were observed frequently for signs of toxic effect on the first day of the test and twice a day (except on weekends or holidays) thereafter. Weights were recorded on the day of dosing and at 7 and 14 days after dosing. After 14 days, all survivors were sacrificed. All rats were necropsied after death or sacrifice.

Separate LD50's were calculated for males and females, based on the 14-day observation period. They were calculated by the moving average method (Thompson, W. R., 1947, Bacteriological Rev. 11: 115-145). Estimates of the slope were made by the formula:

$$\text{slope} = \frac{1.989}{\log \text{LD84} - \log \text{LD16}}$$

This formula was developed by C. S. Weil (of BRRC) who has demonstrated good correlation between this estimated slope and that obtained from probit analysis.

Percutaneous Application

The entire trunk of each rabbit was closely clipped a few days before dosing and was trimmed carefully, as necessary, just before application of the sample. An appropriate amount of sample was applied to the rabbit's back. For each rabbit, the actual amount was recorded on the dose record sheet. Polyethylene sheeting was wrapped around the trunk of the rabbit so that the sample was in contact with the dorsal skin surface. To secure the polyethylene, adhesive tape and plastic ties were added. Saline was added to the powder to moisten it. The rabbit was placed in a restrainer where it remained for 24 hours, after which it was removed and any residual test material carefully wiped off.

Five males and 5 females with abraded skin were dosed at the maximum dosage level required, 2.0 g/kg b.w. Abrasions were made in such a way as to penetrate the stratum corneum but not the dermis. Treated rabbits were observed frequently for signs of toxic effect on the first day of the test and twice daily (except on weekends or holidays) thereafter. Weights were recorded at 0, 7 and 14 days. At the end of 14 days, all survivors were sacrificed. All rabbits were necropsied following sacrifice.

Primary Skin Irritation

The entire trunk of each rabbit was closely clipped a few days before dosing and was trimmed carefully, as necessary, just before application of the test material. One-half gram of the sample was applied to each of 4 sites per rabbit. The powder was moistened with saline. On 2 sites, abrasions were made which penetrated only the stratum corneum. A one-inch square gauze patch was placed over each dose site and was secured by adhesive tape. Plastic sheeting was placed loosely around the trunk and secured. The animal was placed in a restraining device for the 24-hour contact period after which the coverings and excess sample were removed.

NAA Sodium Salt was applied to each of 6 rabbits. Readings were made at 24 and 72 hours after the end of the contact period according to the system of Draize (Draize, J. H., 1959. The Appraisal of Chemicals in Foods, Drugs and Cosmetics, pp. 36-45. Association of Food and Drug Officials of the United States, Austin, TX). The system is shown in Appendix I.

Primary Eye Irritation

Eyes to be dosed were examined using fluorescein stain at least 24 hours before application. If any pre-existing eye injury was apparent, the eye was rejected for use in the test. One-tenth gram of the sample was dosed per eye.

The test material was placed on the everted lower lid of the eye and the lids were held together for one second. A total of 9 eyes were dosed using one eye per rabbit. The remaining eye of each animal served as a control. Six eyes were unwashed and 3 were rinsed with lukewarm water at 20 to 50 seconds after application of the sample.

Readings were made 1, 2, 3, 4, 7, 14, and 21 days later, with fluorescein staining. Grading and scoring were performed by the Draize system (see previous reference) as shown in Appendix II. Any effects not included in the Draize scoring scheme were also noted.

Study Schedule for Experimental Work

Peroral Test: February 9, 1982 to March 1, 1982
Percutaneous Test: February 11, 1982 to March 16, 1982
Dermal Irritation Test: February 22, 1982 to February 25, 1982
Eye Irritation Test: February 15, 1982 to March 8, 1982

Results

Peroral Intubation

Individual results from the LD50 study are given in Table 1 for males and Table 2 for females. A summary is given in Table 3.

Respective peroral LD50's for male and female rats were 1.35 and 0.933 g of NAA Sodium Salt per kg b.w. The estimated slope for the peroral LD50 in males was 10.2 and in females was 4.96.

Signs observed following intubation of NAA Sodium Salt included sluggishness, salivation and convulsions. Deaths occurred at 1.25 hr to 3 days. Most survivors recovered within 24 hours. Necropsy revealed several rats with dark red lungs.

Percutaneous Application

Individual results from the percutaneous study are given in Table 4 (abraded males) and Table 5 (abraded females). The results are summarized in Table 6.

The maximum required dosage, 2.0 g of NAA Sodium Salt/kg b.w. killed 0 of 5 male rabbits with abraded skin and 0 of 5 females with abraded skin. No skin irritation or signs of toxicity were observed and the only gross pathologic finding was dark red lungs.

Primary Skin Irritation

No skin reaction was observed on any of 6 rabbits at 24 or 72 hours after application (see Table 7).

Primary Eye Irritation

Results of eye the irritation are shown in Table 8. All of the dosed eyes had corneal opacity, conjunctival redness, chemosis and discharge, persisting in some cases throughout a 21 day observation period. Five rabbits had necrosis of the nictitating membrane and the eyelids were partially to completely closed, in most cases, for 14 days.

Records

Data from the 4 tests were recorded on loose pages which, along with pertinent correspondence, notes, protocols and reports, will be kept in the BRRC archives (Room 237). Certain related data including preliminary rabbit weights and records of sample receipt (excluding BRRC sample cards) were recorded in bound laboratory notebooks. When completed, these will be submitted to the archives for storage.

Reviewed and Approved by:

Roy C. Myers, B.S.
Study Director

Carrol S. Weil, M.A.
Chief Toxicologist

Fred R. Frank, Ph.D.
Director

Acknowledgements:

Peroral Tests	Susan M. Christopher, B.S. Master Technologist
Percutaneous, Skin and Eye Irritation Tests	Nick S. Bellich Senior Technologist
Pathologic Examination	Edward H. Fowler, Ph.D., D.V.M. Associate Director
Animal Care	Michael J. Cardella, AALAS Cert. III Supervisor I
Archives Supervisor	Roy C. Myers, B.S. Staff Scientist

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Table 1

Individual Results from Single Peroral Doses to Male Rats

Rat Number	Dosage, g/kg b.w.[a]	Rat Weight, g			Approximate Time to Death	Necropsy Findings
		Initial	7 Days	14 Days		
82-16296	2.0	212	-	-	2 hr	Nothing remarkable.
82-16297	2.0	220	-	-	1.5 hr	Nothing remarkable.
82-16298	2.0	207	-	-	1 day	Nothing remarkable.
82-16299	2.0	210	-	-	2 hr	Nothing remarkable.
82-16300	2.0	209	-	-	2 hr	Nothing remarkable.
82-16916	1.4	203	-	-	3 days	Liver pale.
82-16917	1.4	213	-	-	1 day	Nothing remarkable.
82-16915	1.4	214	252	320	-	Nothing remarkable.
82-16914	1.4	200	-	-	3 days	Liver pale.
82-16913	1.4	222	270	339	-	Lungs maroon with patchy discoloration.
82-16361	1.0	221	305	380	-	Nothing remarkable.
82-16359	1.0	225	304	370	-	Nothing remarkable.
82-16362	1.0	224	294	340	-	Lungs mottled, dark red.
82-16358	1.0	228	304	365	-	Lungs mottled, dark red.
82-16360	1.0	228	321	357	-	Nothing remarkable.
82-16303	0.5	216	290	312	-	Lungs red.
82-16302	0.5	215	289	290	-	Lungs dark red.
82-16301	0.5	214	299	353	-	Lungs dark red.
82-16305	0.5	217	297	364	-	Lungs dark red.
82-16304	0.5	212	294	347	-	Lungs dark red.

[a] Dosage given as g of NAA Sodium Salt per kg of body weight; sample delivered as a 15% (w/v) solution in water.

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Table 2

Individual Results from Single Peroral Doses to Female Rats

Rat Number	Dosage, g/kg b.w.[a]	Rat Weight, g			Approximate Time to Death	Necropsy Findings
		Initial	7 Days	14 Days		
82-14990	2.0	215	-	-	1.5 hr	Lungs dark red.
82-15807	2.0	208	-	-	2.5 hr	Nothing remarkable.
82-15809	2.0	204	-	-	2.5 hr	Nothing remarkable.
82-15816	2.0	213	-	-	2.5 hr	Nothing remarkable.
82-16716	2.0	204	-	-	1.25 hr	Nothing remarkable.
82-15815	1.0	202	-	-	1 day	Nothing remarkable.
82-15826	1.0	201	241	251	-	Nothing remarkable.
82-15829	1.0	211	-	-	5 hr	Nothing remarkable.
82-15834	1.0	201	-	-	3 hr	Nothing remarkable.
82-15825	1.0	211	249	273	-	Nothing remarkable.
82-16720	0.5	209	254	278	-	Lungs spotted red to dark red.
82-16719	0.5	204	244	259	-	Lungs spotted red to dark red.
82-16722	0.5	211	250	266	-	Nothing remarkable.
82-16723	0.5	216	263	276	-	Nothing remarkable.
82-16721	0.5	215	269	290	-	Nothing remarkable.

[a]Dosage given as g of NAA Sodium Salt per kg of body weight; sample delivered as a 15% (w/v) solution in water.

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Table 3

Summary of Results from Single Peroral Doses to Rats

Dosage, g/kg b.w.	Dead/ Dosed	Weight Change, g		Signs of Toxicity
		7 Days	14 Days	
Male Rats				
2.0	5/5	-	-	Salivation at 5 min; sluggishness at 10 min; low carriage, twitching movements at 15 min; torsion convulsions at 1.5 hr; death of 4 within 2 hr.
1.4	3/5	38 and 48 (mean=43)	106 and 117 (mean=112)	Sluggishness at 10 min; low carriage at 45 min; death of 3 at 1 to 3 days. Survivors recovered at 24 hr.
1.0	0/5	70 to 93 (mean=80)	116 to 159 (mean=137)	Sluggishness at 5 min. Recovery at 1 hr to 1 day.
0.5	0/5	74 to 85 (mean=79)	75 to 147 (mean=118)	Salivation at 5 min; sluggishness at 10 min. Recovery at 2 hr.
Female Rats				
2.0	5/5	-	-	Sluggishness at 5 min; twitching, low carriage at 10 min; convulsions at 1.5 hr; death at 1.25 to 2.5 hr.
1.0	3/5	38 and 40 (mean=39)	50 and 62 (mean=56)	Sluggishness at 10 min; death of 3 at 3 hr to 1 day. Survivors recovered at 1 day.
0.5	0/5	39 to 54 (mean=45)	55 to 75 (mean=63)	Sluggishness at 10 min. Recovery at 1 hr to 1 day.

LD50's with 95% Confidence Limits:
Males: 1.35 (1.12 to 1.64) g of NAA Sodium Salt/kg b.w.; sample delivered as a 15% (w/v) solution in water.
Females: 0.933 (0.631 to 1.38) g of NAA Sodium Salt/kg b.w.; sample delivered as a 15% (w/v) solution in water.

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Table 4

Individual Results from Single Doses to Abraded Skin of Male Rabbits

Rabbit Number	Dosage, g/kg b.w.[a]	Rabbit Weight, g			Approximate Time to Death	Skin Irritation	Necropsy Findings
		Initial	7 Days	14 Days			
82-14006	2.0	2274	2308	2510	-	None noted.	Lungs mottled, discolored.
82-14021	2.0	2326	2392	2691	-	None noted.	Lungs with patchy discoloration.
82-14002	2.0	2144	2255	2393	-	None noted.	Nothing remarkable.
82-14012	2.0	2149	2235	2401	-	None noted.	Nothing remarkable.
82-14038	2.0	2123	2134	2141	-	None noted.	Lungs mottled, discolored.

[a]Dosage given as g of NAA Sodium Salt per kg b.w; sample moistened with saline to form a paste.

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Table 5

Individual Results from Single Doses to Abraded Skin of Female Rabbits

Rabbit Number	Dosage, g/kg b.w.[a]	Rabbit Weight, g			Approximate Time to Death	Skin Irritation	Necropsy Findings
		Initial	7 Days	14 Days			
82-13854	2.0	2486	2641	2553	-	None noted.	Nothing remarkable.
82-13925	2.0	2451	2677	3011	-	None noted.	Lungs with patchy discoloration.
82-14057	2.0	2266	2244	2287	-	None noted.	Lungs discolored.
82-14067	2.0	2284	2432	2739	-	None noted.	Lungs with patchy discoloration.
82-13907	2.0	2609	2746	2922	-	None noted.	Nothing remarkable.

[a]Dosage given as g of NAA Sodium Salt per kg b.w; sample moistened with saline to form a paste.

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04-22-82

Table 6

Summary of Results from Single Application to Rabbit Skin

Dosage, g/kg b.w.	Dead/ Dosed	Weight Change, g 7 Days	Weight Change, g 14 Days	Signs
			Male Rabbits; Abraded Skin	
2.0	0/5	11 to 111 (mean=62)	18 to 365 (mean=224)	None noted.
			Female Rabbits: Abraded Skin	
2.0	0/5	-22 to 226 (mean=129)	21 to 560 (mean=283)	None noted.

LD50's, g/kg:
Male, Abraded Skin; greater than 2.0 g NAA Sodium Salt/kg b.w.; sample moistened with sufficient saline to form a paste.
Female, Abraded Skin: greater than 2.0 g NAA Sodium Salt/kg b.w.; sample moistened with sufficient saline to form a paste.

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04-22-82

Table 7

Primary Skin Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.5 g of sample per site, moistened with saline Sample No.: 44-356

Erythema & Eschar	Time	Date: 2/22/82 Rabbit No: 82-13989 (Female) Score	Date: 2/22/82 Rabbit No: 82-13990 (Female) Score	Date: 2/22/82 Rabbit No: 82-13991 (Female) Score	Date: 2/22/82 Rabbit No: 82-13992 (Female) Score	Date: 2/22/82 Rabbit No: 82-13914 (Female) Score	Date: 2/22/82 Rabbit No: 82-13927 (Female) Score	Average Score
Intact-Site #1	24 hr	0	0	0	0	0	0	0.0
Intact-Site #1	72 hr	0	0	0	0	0	0	0.0
Intact-Site #2	24 hr	0	0	0	0	0	0	0.0
Intact-Site #2	72 hr	0	0	0	0	0	0	0.0
Abraded-Site #3	24 hr	0	0	0	0	0	0	0.0
Abraded-Site #3	72 hr	0	0	0	0	0	0	0.0
Abraded-Site #4	24 hr	0	0	0	0	0	0	0.0
Abraded-Site #4	72 hr	0	0	0	0	0	0	0.0
							Subtotal of Averages:	0.0
Edema Formation	Time							
Intact-Site #1	24 hr	0	0	0	0	0	0	0.0
Intact-Site #1	72 hr	0	0	0	0	0	0	0.0
Intact-Site #2	24 hr	0	0	0	0	0	0	0.0
Intact-Site #2	72 hr	0	0	0	0	0	0	0.0
Abraded-Site #3	24 hr	0	0	0	0	0	0	0.0
Abraded-Site #3	72 hr	0	0	0	0	0	0	0.0
Abraded-Site #4	24 hr	0	0	0	0	0	0	0.0
Abraded-Site #4	72 hr	0	0	0	0	0	0	0.0
							Subtotal of Averages:	0.0

Specific Effects/Remarks:

Total of Averages: 0.0

Primary Irritation Score = 0.0

PC/jlc/2034A-1
04-15-82

Appendix II

Draize Scoring System for Eye Irritation

I. CORNEA

(A) OPACITY-DEGREE OF DENSITY (AREA TAKEN FOR READING)

Scattered or diffuse area-details of iris clearly visible-1.
Easily discernible translucent areas, details of iris slightly obscured-2.
Opalescent areas, no details of iris visible, size of pupil barely discernible-3.
Opaque, iris invisible-4.

(B) AREA OF CORNEA INVOLVED

One quarter (or less) but not zero-1.
Greater than one quarter-less than one-half-2.
Greater than one-half less than three quarters-3.
Greater than three quarters up to whole area-4.
Score equals AXBX5 Total maximum=80.

II. IRIS

(A) VALUES

Folds above normal, congestion, swelling, circumcorneal injection (any one or all of these or combination of any thereof), iris still reacting to light (sluggish reaction is positive)-1.
No reaction to light, hemorrhage: gross destruction (any one or all of these)-2.
Score AX5 Total possible maximum=10.

III. CONJUNCTIVAE

(A) REDNESS (REFERS TO PALPEBRAL CONJUNCTIVAE ONLY)

Vessels definitely injected above normal-1.
More diffuse, deeper crimson red, individual vessels not easily discernible-2.
Diffuse beefy red-3.

(B) CHEMOSIS

Any swelling above normal (includes nictitation membrane)-1.
Obvious swelling with partial everson of the lids-2.
Swelling with lids about half closed-3.
Swelling with lids about half closed to completely closed-4.

(C) DISCHARGE

Any amount different from normal (does not include small amount observed in inner canthus of normal animals)-1.
Discharge with moistening of the lids and hairs just adjacent to the lids-2.
Discharge with moistening of the lids and considerable area around the eye-3.
Score (A+B+C)X2 Total Maximum = 20.

The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctivae.

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UNION CARBIDE

BUSHY RUN RESEARCH CENTER

R. D. 4, Mellon Road, Export, Pennsylvania 15632 Telephone (412) 327-1020

Quality Assurance Unit Study Inspection Summary

Test Substance: Naphthalene Acetic Acid Sodium Salt

Study: Acute Toxicity and Irritancy

Study Director: R. C. Myers, B.S.

The Quality Assurance Unit of BRRC conducted the inspections listed below and reported the results to the study director and to management on the dates indicated. It is the practice of this Quality Assurance Unit to report the results of each inspection to both the study director and management.

Inspection Date	Inspection Type	Date QAU Report Issued To Study Director	Date QAU Report Issued To Management
1-14-82	Standard Protocol Amendment	1-14-82	1-14-82
2-11-82	Event - Percutaneous Dosing	2-11-82	2-23-82
2-15 and 2-16-82	Event - Eye Irritation Test	2-19-82	4-20-82
2-22-82	Event - Skin Irritation Test	2-23-82	4-20-82
4-26-82	Final Data and Final Report	4-26-82	4-28-82

Daniel L. Geary / J. R. Bernard 4-28

Quality Assurance Officer Date

LJC:acc

Table 8

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14007; male (left eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	3	3	3	3	3	3	3	1
B. Area Involved:	4	4	4	4	2	1	1	1
Score (AXBX5):	60	60	60	60	30	15	15	5
II. Iris								
A. Values:	1	1	1	1	1	1	0	0
Score (AX5):	5	5	5	5	5	5	0	0
III. Conjunctivae								
A. Redness:	2	2	2	2	2	2	1	1
B. Chemosis:	1	2	2	2	1	2	2	1
C. Discharge:	2	3	3	3	3	3	2	1
Score [(A+B+C)X2]:	10	14	14	14	12	14	10	6
TOTAL SCORE (I+I+III):	75	79	79	79	47	34	25	11
FLUORESCEIN EXAMINATION:	100%	100%	80%	75%	35%	20%	5%	20%

SPECIFIC EFFECTS/REMARKS: Nictitating membrane with necrosis; lids partially closed through 14 days.

(Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14011; male (right eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	1	1	1	1	1	1	0	0
B. Area Involved:	4	2	2	2	1	1	0	0
Score (AXBX5):	20	10	10	10	5	5	0	0
II. Iris								
A. Values:	1	1	1	1	1	0	0	0
Score (AX5):	5	5	5	5	5	0	0	0
III. Conjunctivae								
A. Redness:	2	2	2	2	1	0	0	0
B. Chemosis:	2	2	2	2	0	0	0	0
C. Discharge:	3	3	3	3	0	0	0	0
Score [(A+B+C)X2]:	14	14	14	14	2	0	0	0
TOTAL SCORE (I+I+III):	39	29	29	29	12	5	0	0
FLUORESCEIN EXAMINATION:	100%	30%	30%	30%	15%	10%	0%	0%

SPECIFIC EFFECTS/REMARKS: Nictitating membrane with necrosis; lids partially closed through 10 days.

(Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14014; male (left eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	3	2	2	2	3	3	2	2
B. Area Involved:	4	4	4	4	2	2	1	1
Score (AXBX5):	60	40	40	40	30	30	10	10
II. Iris								
A. Values:	1	1	1	1	1	0	0	0
Score (AX5):	5	5	5	5	5	0	0	0
III. Conjunctivae								
A. Redness:	3	2	2	2	2	1	1	1
B. Chemosis:	3	2	2	2	2	2	2	2
C. Discharge:	3	3	3	3	3	3	2	2
Score [(A+B+C)X2]:	18	14	14	14	14	12	10	10
TOTAL SCORE (I+I+III):	83	59	59	59	49	42	20	20
FLUORESCEIN EXAMINATION:	100%	100%	85%	85%	35%	25%	25%	10%

SPECIFIC EFFECTS/REMARKS: Conjunctivae and nictitating membrane with necrosis; lids partially closed through 14 days. Vascularization noted at 7 through 21 days.

(Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14053; female (left eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	4	4	4	4	4	4	4	4
B. Area Involved:	4	4	4	4	3	3	4	4
Score (AXBX5):	80	80	80	80	60	60	80	80
II. Iris								
A. Values:	*	*	*	*	*	*	*	*
Score (AX5):	5	10	10	10	10	10	-	-
III. Conjunctivae								
A. Redness:	1	1	1	1	1	1	2	1
B. Chemosis:	4	4	3	3	3	3	3	3
C. Discharge:	3	3	3	3	3	3	3	3
Score [(A+B+C)X2]:	16	16	14	14	14	14	16	14
TOTAL SCORE (I+I+III):	101	106	104	104	84	84	96	94
FLUORESCEIN EXAMINATION:	100%	90%	85%	85%	60%	60%	100%	100%

SPECIFIC EFFECTS/REMARKS: Lids closed throughout.

* Only a small portion of iris was seen because of closure of lids.

(Continued)

Table 8 (Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed.

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14054; female (left eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	2	3	3	3	3	3	3	3
B. Area Involved:	4	4	4	4	3	2	3	4
Score (AXBX5):	40	60	60	60	45	30	45	60
II. Iris								
A. Values:	1	1	1	1	1	0	0	0
Score (AX5):	5	5	5	5	5	0	0	0
III. Conjunctivae								
A. Redness:	1	1	1	1	1	1	1	1
B. Chemosis:	2	2	1	1	2	2	2	2
C. Discharge:	3	3	3	3	3	3	3	3
Score [(A+B+C)X2]:	12	12	10	10	12	12	12	12
TOTAL SCORE (I+I+III):	57	77	75	75	62	42	57	72
FLUORESCEIN EXAMINATION:	100%	100%	100%	100%	75%	45%	70%	100%

SPECIFIC EFFECTS/REMARKS: Lids closed to partially closed through 14 days; Vascularization at 14 and 21 days.

(Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed.

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14056; female (right eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	1	1	1	1	0	0	0	0
B. Area Involved:	2	1	1	1	0	0	0	0
Score (AXBX5):	10	5	5	5	0	0	0	0
II. Iris								
A. Values:	1	1	1	1	1	0	0	0
Score (AX5):	5	5	5	5	5	0	0	0
III. Conjunctivae								
A. Redness:	2	2	2	2	0	0	0	0
B. Chemosis:	1	1	1	1	0	0	0	0
C. Discharge:	3	3	2	2	0	0	0	0
Score [(A+B+C)X2]:	12	12	10	10	0	0	0	0
TOTAL SCORE (I+I+III):	27	22	20	20	5	0	0	0
FLUORESCEIN EXAMINATION:	50%	10%	10%	5%	0%	0%	0%	0%

SPECIFIC EFFECTS/REMARKS: Nictitating membrane with necrosis; lids closed through 72 hr.

(Continued)

Table 8 (Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed. Sample then washed from eye.

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14020; male (right eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	1	1	1	1	1	0	0	0
B. Area Involved:	2	1	1	1	1	0	0	0
Score (AXBX5):	10	5	5	5	5	0	0	0
II. Iris								
A. Values:	1	1	0	0	0	0	0	0
Score (AX5):	5	5	0	0	0	0	0	0
III. Conjunctivae								
A. Redness:	2	1	1	1	1	0	0	0
B. Chemosis:	2	2	1	1	1	0	0	0
C. Discharge:	3	3	2	2	0	0	0	0
Score [(A+B+C)X2]:	14	12	8	8	4	0	0	0
TOTAL SCORE (I+I+III):	29	22	13	13	9	0	0	0
FLUORESCEIN EXAMINATION:	33%	20%	15%	10%	2%	0	0	0

SPECIFIC EFFECTS/REMARKS: Lids closed at 24 and 48 hr.

(Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed. Sample then washed from eye.

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14031; male (left eye)

OBSERVATION	OBSERVATION TIMES					
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days*
I. Cornea						
A. Opacity:	2	2	2	1	1	1
B. Area Involved:	3	3	3	3	2	1
Score (AXBX5):	30	30	30	15	10	5
II. Iris						
A. Values:	1	1	1	1	1	0
Score (AX5):	5	5	5	5	5	0
III. Conjunctivae						
A. Redness:	1	1	1	1	2	1
B. Chemosis:	1	1	1	1	1	0
C. Discharge:	3	3	3	3	1	1
Score [(A+B+C)X2]:	10	10	10	10	8	4
TOTAL SCORE (I+I+III):	45	45	45	30	23	9
FLUORESCEIN EXAMINATION:	75%	65%	65%	60%	35%	20%

SPECIFIC EFFECTS/REMARKS: Lids closed through 7 days; nictitating membrane with necrosis.
* This rabbit developed diarrhea by the 24 hr observation period; it was dead at 11 days.

Table 8 (Continued)

Table 8 (Continued)

Primary Eye Irritation - Draize Procedure

Material: NAA Sodium Salt; 0.1 g of sample dosed. Sample then washed from eye.

Date Applied: February 15, 1982 Sample No: 44-356 Rabbit No: 82-14063; female (right eye)

OBSERVATION	OBSERVATION TIMES							
	24 Hr	48 Hr	72 Hr	4 Days	7 Days	10 Days	14 Days	21 days
I. Cornea								
A. Opacity:	2	2	2	2	2	2	2	2
B. Area Involved:	4	3	3	3	2	1	1	1
Score (AXBX5):	40	30	30	30	20	10	10	10
II. Iris								
A. Values:	1	1	1	1	1	0	0	0
Score (AX5):	5	5	5	5	5	0	0	0
III. Conjunctivae								
A. Redness:	2	1	1	1	1	1	1	1
B. Chemosis:	3	3	3	3	2	2	2	2
C. Discharge:	3	3	3	3	3	1	3	3
Score [(A+B+C)X2]:	16	14	14	14	12	8	12	12
TOTAL SCORE (I+I+III):	61	49	49	49	37	18	22	22
FLUORESCEIN EXAMINATION:	75%	75%	65%	65%	45%	10%	5%	5%

SPECIFIC EFFECTS/REMARKS: Lids partially to completely closed throughout 21 day observation period. Vascularization 7 through 21 days.

Appendix I

Draize Scoring System for Skin Irritation

Evaluation of skin reactions	*Value*[1]
Erythema and eschar formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injury in depth	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 millimeter)	3
Severe edema (raised more than 1-millimeter and extending beyond the area of exposure)	4

[1]The "value" recorded for each reading is the average value of the six or more animals subject to the test.

Evaluate the reactions of the abraded skin at 24 hours and 72 hours, as described in this paragraph. Add the values for erythema and Eschar formation at 24 hours and at 72 hours for intact skin to the values on abraded skin at 24 hours and at 72 hours (four values).Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score.
EXAMPLE:

	Exposure time	Exposure unit
Erythema and eschar formation:	Hours	Value
Intact skin	24	2
Do	72	1
Abraded skin	24	3
Do	72	2
Subtotal		8
Edema formation:		
Intact skin	24	0
Do	72	1
Abraded skin	24	1
Do	72	2
Subtotal		4
Total		12

Primary irritation score is 12 ÷ 4 = 3.

Triage of 8(e) Submissions

Date sent to triage: 2/5/96

NON-CAP CAP

Submission number: 12848 A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1,2 **pages** 1, 2, 3, tab

Notes: 2-sided.

Contractor reviewer : LPS **Date:** 5/11/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 0892-12898 SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: Union Carbide Chemicals and Plastics Company Inc.

SUB. DATE: 08/21/92 OTS DATE: 08/27/92 CSRAD DATE: 03/23/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0539) REFER TO CHEMICAL SCREENING
(0578) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER RECIPIENTS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:

CAS#
61-31-4

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
(0209)	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
(0243)	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:

NON-CBI INVENTORY
(YES)
NO
DETERMINE

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
RAT
RBT

TOXICOLOGICAL CONCERN:
(LOW) Acute Oral Toxicity, Acute Dermal Toxicity, Dermal Irritation
MED
(HIGH) Ocular Irritation

USE:

PRODUCTION:

CAS SR

COMMENTS

#12848A
H

Ocular irritation is of high concern based on necrosis (conjunctivae and/or nictating membrane) in 5/9 rabbits. Irritation included moderate to severe corneal opacity, iritis, and conjunctival irritation which persisted in 5 rabbits through 21 days.

L

Acute oral toxicity is of low concern based on a calculated LD_{50} of 1350 mg/kg in male rats, and 944 mg/kg in females. Mortality and corresponding doses (mg/kg) were 0/10 (500), 3/10 (1000), 3/5 males (1400) and 10/10 (2000). Clinical signs included sluggishness (all doses) and convulsions (2000). Dark red lungs were observed in males (500 and 1000) and females (500 and 2000).

L

Acute dermal toxicity is of low concern based on no mortality (0/10) in rats (5/sex) exposed to 2000 mg/kg. Discolored and mottled lungs were observed at necropsy.

L

Dermal irritation is of low concern based on no irritation in 6/6 rabbits.